

DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 5: DOCUMENTATION	Course Number:
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DOCUMENTATION	
Obtain a copy of ISO 10013 and become familiar with it.	Slide #5-1
DOCUMENTATION Stress the fact that poor documentation and documentation-related activities have historically been the number one reason for non-certification. Discuss the figure shown in the student notes for this slide. ISO 10013, "Guidelines for Developing Quality Manuals," gives guidance on the structure and development of the necessary documentation for a quality system. The document "...provides guidelines for the development, preparation, and control of quality manuals tailored to the specific needs of the user. The resultant quality manual will reflect documented quality system procedures required by the ISO 9000 series. Detailed work instructions, quality plans, and brochures are not covered by this standard."	Slide #5-2
DOCUMENTATION (CONCLUDED) Continue the discussion of the "tiers" of documentation and the reason for the usual order of development. The order of development of the documentation will vary from organization to organization. However, experience has shown that the most frequent order of development is the following: <ol style="list-style-type: none"> 1. Quality Manual 2. Work Instructions 3. Procedures The rationale for development in this order is that the organization must initially determine the intent of each of the elements of ISO 9001, 9002, or 9003 and how each element applies to its operation. It must state that it will comply with this intent. This usually leads to a gap analysis, which highlights shortcomings in the present system. This gap analysis should point out shortcomings in both work habits and procedural activities. Work instruction gaps are analyzed and then worked on to attempt closure. After	Slide #5-3

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<p>DOCUMENTATION (CONTINUED)</p> <p>sufficient progress has been made on the work instructions, it is then easier to begin examining the procedures. One psychological advantage of following this order is that each department first "gets its house in order," and the negative blaming of other departments is diminished. This leads to more openness in working together to develop the necessary procedures.</p>	Slide #5-3 (concluded)
<p>THE QUALITY MANUAL</p> <p>Discuss how the quality manual relates to the 20 elements of ISO 9001.</p> <p>As the quality manual is being developed, it will become clear where procedures are needed. Reference to these procedures should be made in the wording of the manual. If the procedures are non-existent, an indication is made that they are to be developed.</p> <p>A quality manual should consist of, or refer to, the documented quality system procedures intended for the overall planning and administration of activities that impact quality within an organization. A quality manual should cover all the applicable elements of the quality system standard required for an organization.</p>	Slide #5-4

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<p>THE QUALITY MANUAL (CONCLUDED)</p> <p>In some situations, related quality system procedures and the manual may be identical, but some degree of tailoring is usually required. Normally, the manual references procedures that support the compliance with the standard. These procedures in turn reference work instructions that detail how specific tasks are to be performed. This leads to a three-tiered structure of documentation depicted in Annex A of ISO 10013. ISO 10013 includes a note that states "inclusion of proprietary information is at the discretion of the organization."</p>	Slide #5-4 (concluded)
<p>QUALITY MANUAL PURPOSE</p> <p>Stress that the quality manual should be the <i>working document</i> for the quality system and not a separate entity from the routine management of the organization.</p> <p>When developing documentation, the organization should consider that the purposes of a quality manual are as follows (but are not limited to only these):</p> <ul style="list-style-type: none"> • Establishing and communicating the company's policy, procedures, and requirements • Implementing an effective quality system • Providing improved control of practices and facilitating assurance activities • Providing the documented bases for auditing quality systems • Providing continuity of the quality system and its requirements during changing circumstances • Training personnel in the quality system requirements and method • Presenting their quality system for external purposes, such as demonstrating compliance with ISO 9001, 9002, or 9003. • Demonstrating compliance of their quality system with required quality standards in contractual situations 	Slide #5-5

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<p>QUALITY MANUAL STRUCTURE</p> <p>The quality manual could contain all procedures and work instructions; however, the larger the organization, the more unwieldy this becomes. It is usually best to allow the manual to reflect the adherence to ISO 9001 with reference to procedures and/or work instructions. Separate manuals may be developed for internal and external use. A "Quality Management Manual" for use internally may contain proprietary information while a "Quality Assurance Manual" for external use may not contain proprietary information.</p> <p>Although the quality manual may only reference procedures, it may have the following characteristics:</p> <ul style="list-style-type: none"> • Be a direct compilation of the quality system procedures • Be a grouping or section of the quality system procedures • Be a series of procedures for specific facilities/applications • Be more than one document or level • Have a common core with tailored appendices • Stand alone or otherwise • Have other numerous possible derivations based upon organizational need <p>The simple term "quality manual" is typically used when the same manual is employed for both quality management and quality assurances purposes. In situations in which a distinction of content or usage is needed, the more specific terms "quality management manual" and "quality assurance manual" should be used. If two manuals are used, they should not be in conflict.</p> <p>Any quality manual should identify the management functions, address the documented quality system/procedures, and briefly cover all the applicable requirements of the quality system standard selected by the organization.</p> <p>An example of a section of a quality manual and its relation to the corresponding clause of ISO 9001 is presented in Annex C of ISO 10013.</p>	<p>Slide #5-6</p>

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<p>QUALITY MANUAL STRUCTURE (CONTINUED)</p> <p>ISO 10013 gives guidance on the process of preparing a quality manual. It advises that the coordination be given to a competent person or group that has the power and resources to manage the project.</p> <p>The following steps are given for reference:</p> <ul style="list-style-type: none"> • Establish and list existing applicable quality system policies, objectives, and procedures or develop plans for such • Decide which quality system elements apply according to the quality system standard selected • Obtain data about the quality system from relevant sources such as current users • Request and obtain additional source documentation or references from operational units • Determine the format and structure for the intended manual • Classify existing documents in accordance with the intended format and structure • Use any other method suitable within the organization to complete the quality manual draft <p>Whenever appropriate and to avoid unnecessary document volume, references to existing recognized standards or documents available to the quality manual user should be incorporated (ASTM, SAE, etc.).</p> <p>Prior to issuing the manual, the document should be subjected to a final review by responsible individuals to ensure clarity, accuracy, suitability, and proper structure. The intended users should also have the opportunity to assess and comment on the usability of the document. In fact, experience has shown that the most accurate and expeditious manner in which to develop procedure and work instructions is to have the personnel actually performing the work to develop them.</p> <p>ISO 10013 also gives advice that is essentially a reiteration of the information found in Section 4.5 of ISO 9001, 9002, and 9003.</p>	<p>Slide #5-6 (continued)</p>

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<p>QUALITY MANUAL STRUCTURE (CONCLUDED)</p> <p>A quality manual should normally contain the following:</p> <ul style="list-style-type: none"> • The title, scope, and the field of application • The table of contents of the manual • The introductory pages about the organization concerned and the manual itself • The quality policy and objectives of the organization • The description of the organization, responsibilities, and authorities • A description of the elements of the quality system and/or references to quality system procedures • A definitions section, if appropriate • A guide to the quality manual, if appropriate (see clause 7-9) • An appendix for supportive data, if appropriate <p>Each of the above is discussed in ISO 10013, which should be referred to as the manual is being developed. ISO 10013 has limited information on procedures and work instructions.</p>	Slide #5-6 (concluded)
<p>DEVELOPING DOCUMENTATION</p> <p>Careful coordination and inclusion of all departments is crucial at the outset of development of documentation.</p> <p>One of the first implementation processes is the gap analysis, which is performed to determine the gaps between an organization's current processes and procedures and those required by ISO 9001.</p> <p>The gaps could fall into the following areas:</p> <ul style="list-style-type: none"> • Document gaps • Record gaps • Interface gaps <p>There may be other external that should be included, such as statutory or regulatory requirements.</p> <p>The Federal Acquisition Regulation requirements for the Government is an example of statutory requirements. OSHA workplace safety requirements are an example of regulatory requirements.</p>	Slide #5-7

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DEVELOPING DOCUMENTATION (CONCLUDED) Other possible gaps include ensuring that there are no gaps between the following: <ul style="list-style-type: none"> • Existing documents and actual quality system operations • Existing document record requirements and actual records 	Slide # 5-7 (concluded)